Overview of the Family Smoking Prevention and Tobacco Control Act

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law on June 22, 2009. It gives the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health.

The Tobacco Control Act:

- Recognizes that virtually all new users of tobacco products are under 18—the minimum legal age to purchase these products. Many new users will become addicted before they are old enough to understand the risks and ultimately may die too young of tobacco-related diseases. The Tobacco Control Act seeks to, among other things, prevent and reduce tobacco use by young people.
- Recognizes that tobacco products are legal products available for adult use, prohibits false or misleading labeling and advertising for tobacco products and provides the tobacco industry with several mechanisms to submit an application to FDA for new products or tobacco products with modified risk claims.
- Gives FDA enforcement authority as well as a broad set of sanctions for violations of the law and directs FDA to contract with states to assist FDA with retailer inspections.

This overview highlights some of the provisions of the Tobacco Control Act and is not intended to be a comprehensive guide or to reflect FDA's interpretation of the Tobacco Control Act. For complete information, you must read the entire law. For your convenience, in the text below we provide the section number of the Tobacco Control Act.

What the Tobacco Control Act Does

Restricts cigarettes and smokeless tobacco retail sales to youth by directing FDA to issue regulations which, among other things:

- Require proof of age to purchase these tobacco products – the federal minimum age to purchase is 18—Sec. 102
- Require face-to-face sales, with certain exemptions for vending machines and self-service displays in adult-only facilities—Sec. 102
- Ban the sale of packages of fewer than 20 cigarettes—Sec. 102

Restricts tobacco product advertising and marketing to youth by directing FDA to issue regulations which, among other things:

- Limit color and design of packaging and advertisements, including audio-visual advertisements—Sec. 102 (However, implementation of this provision is uncertain due to pending litigation. See *Discount Tobacco City & Lottery v. USA*, formerly *Commonwealth Brands v. FDA*.)
- Ban tobacco product sponsorship of sporting or entertainment events under the brand name of cigarettes or smokeless tobacco—Sec.102

- Ban free samples of cigarettes and brand-name non-tobacco promotional items—Sec. 102

Note: Among its many provisions, the Tobacco Control Act required FDA to reissue its 1996 final regulations aimed at restricting the sale and distribution of cigarette and smokeless tobacco products.–Sec. 102

The Tobacco Control Act specifically:

- Prohibits "reduced harm" claims including "light," "low," or "mild," without an FDA order to allow marketing—Sec. 911 of the *Federal Food, Drug, and Cosmetic Act* (FDCA)
- Requires industry to submit marketing research documents—Sec. 904 of the FDCA

Requires bigger, more prominent warning labels for cigarettes and smokeless tobacco products:

(However, the implementation date of more prominent warning labels for cigarettes is uncertain, due to ongoing proceedings in the case of *R. J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration*, No, 11-1482 (D.D.C.), *on appeal*, No, 11-5332 (D.C.Cir.).)

- Packaging and advertisements for cigarettes and smokeless tobacco must have revised warning labels with a larger font size. Font colors are limited to white on a black background or black on a white background.—Sec. 201 and 204
- Cigarette package health warnings will be required to cover the top 50 percent of both the front and rear panels of the package, and the nine specific warning messages must be equally and randomly displayed and distributed in all areas of the United States. These messages must be accompanied by color graphics showing the negative health consequences of smoking cigarettes.—Sec. 201
- Smokeless tobacco package warnings must cover 30 percent of the two principal display panels, and the four specific required messages must be equally and randomly displayed and distributed in all areas of the United States.—Sec. 204

Gives FDA authority over, among other things:

- Registration and inspection of tobacco companies—Sec. 905 of the FDCA
  - > Requires owners and operators of tobacco companies to register annually and be subject to inspection every 2 years by FDA.
- Standards for tobacco products—Sec. 907 of the FDCA
  - > Allows FDA to require standards for tobacco products (for example, tar and nicotine levels) as appropriate to protect public health.
  - > Bans cigarettes with characterizing flavors (except menthol and tobacco).
- "Premarket Review" of new tobacco products—Sec. 910 and 905 of the FDCA
  - > Requires manufacturers who wish to market a new tobacco product to obtain a marketing order from FDA prior to marketing that new product.
- "Modified risk" products—Sec. 911 of the FDCA
  - > Requires manufacturers who wish to market a tobacco product with a claim of reduced harm to obtain a marketing order from FDA.
- Enforcement action plan for advertising and promotion restrictions—Sec. 105
  - > FDA published a document entitled "Enforcement Action Plan for Promotion and Advertising Restrictions."
  - > The action plan details FDA's current thinking on how it intends to enforce certain requirements

under the Tobacco Control Act.

The Tobacco Control Act also requires

- Tobacco industry must disclose research on the health, toxicological, behavioral, or physiologic effects of tobacco use.—Sec. 904 of the FDCA
- Tobacco industry must disclose information on ingredients and constituents in tobacco products, and must notify FDA of any changes.—Sec. 904 of the FDCA

How FDA oversees the implementation of the Tobacco Control Act

Among other things, FDA:

- Established the Center for Tobacco Products to implement the Tobacco Control Act—Sec. 901 of the FDCA
- Established the Tobacco Products Scientific Advisory Committee to provide advice, information, and recommendations to the FDA—Sec. 917 of the FDCA
- Assesses user fees on tobacco product manufacturers and importers based on their market share. The fees are used to fund FDA activities related to the regulation of tobacco products—Sec. 919 of the FDCA
- Reports to Congress on how best to encourage companies to develop innovative products that help people stop smoking—Sec. 918 of the FDCA
- Issues regulations and conducts inspections to investigate illicit trade in tobacco products—Sec. 920 of the FDCA
- Convenes a panel of experts to study the public health implications of raising the minimum age to purchase tobacco products—Sec. 104

Limits on FDA's authority

FDA cannot:

- Ban certain specified classes of tobacco products—Sec. 907 of the FDCA
- Require the reduction of nicotine yields to zero—Sec. 907 of the FDCA
- Require prescriptions to purchase tobacco products—Sec. 906 of the FDCA
- Ban face-to-face tobacco sales in any particular category of retail outlet—Sec. 906 of the FDCA

The Tobacco Control Act preserves the authority of state, local, and tribal governments to regulate tobacco products in certain specific respects. It also prohibits, with certain exceptions, state and local requirements that are different from, or in addition to, requirements under the provisions of the FDCA relating to specified areas.

For more information visit www.fda.gov/TobaccoControlAct.

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